

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**APPLICATION NUMBER: 020819**

**MICROBIOLOGY REVIEW(S)**

## REVIEW FOR HFD-510

OFFICE OF NEW DRUG CHEMISTRY  
MICROBIOLOGY STAFF HFD-805  
Microbiologist's Review #1 of NDA 20-819  
September 17, 1997

A. 1. APPLICATION NUMBER: 20-819

APPLICANT: Abbott Laboratories  
200 Abbott Park Road, D-389 AP30  
Abbott Park IL, 60064-3537

2. PRODUCT NAME: Paracalcin Injection

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION: Paracalcin (5 µg/mL) in single dose 1 ml, 2mL, and 5 mL vials and ampules for IV injection.

4. METHODS OF STERILIZATION: \_\_\_\_\_

APPEARS THIS WAY  
ON ORIGINAL

5. PHARMALOGICAL CATAGORY and/or PRINCIPLE INDICATION: Vitamin D analog indicated for the prevention and treatment of renal osteodystrophy and secondary hyperthyroidism encountered with chronic renal failure.

6. DRUG PRIORITY CLASSIFICATION: S

B. 1. DATE OF INITIAL SUBMISSION: January 17, 1997

APPEARS THIS WAY  
ON ORIGINAL

2. DATE OF AMENDMENT: August 1, 1997

3. DATE OF CONSULT: February 10, 1997

4. ASSIGNED FOR REVIEW: February 13, 1997

C. REMARKS: This review incorporates both the initial January 17, 1997 submission for the ampule configurations, and the August 1, 1997 amendment to provide for the ampule configurations. No consult request was submitted for the August 1, 1997 amendment.

A description of the Rocky Mount manufacturing facility, \_\_\_\_\_, was duplicated and included in the NDA submission. \_\_\_\_\_

**D. CONCLUSIONS:**

The submission is recommended for approval for microbiology issues concerning sterility assurance.

APPEARS THIS WAY  
ON ORIGINAL

APPROVED  
ON 9/17/97

APPROVED  
ON 9/17/97

/S/ 9/17/97  
Neal Sweeney, Ph.D.

/S/ 9/23/97

APPROVED  
ON 9/23/97

cc: NDA 20-819  
HFD-510/Division File  
HFD-510/R. Hedin/S. Markofsky  
HFD-805/Consult File/N. Sweeney

Drafted by: N. Sweeney, September 17, 1997  
R/D initialed by P. Cooney, September 17, 1997

APPROVED  
ON 9/23/97

APPROVED  
ON 9/23/97